PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 3110.03US02
Kuslich	Confirmation No.: 6813
Application No.: 10/702,096	Examiner: Alvin Stewart
Filed: November 5, 2003	Group Art Unit: 3738

For: SEMI-BIOLOGICAL INTERVERTEBRAL DISC REPLACEMENT SYSTEM

DECLARATION PURSUANT TO 37 C.F.R.§ 1.132

I, Michael MacMillan, M.D., declare under penalty of perjury that the following is true and correct to the best of my knowledge, information and belief:

1. I graduated from University of North Carolina, School of Medicine, in 1980.

2. I am an Orthopaedic Surgeon specializing in the treatment of spinal disorders.

3. I have read and understood United States Patent Application No. 10/702,096 to Kuslich. ("the Kuslich Application")

4. I have read and understood United States Patent Application No. 09/827,427 to Belef et al.

5. The Kuslich Application describes methods and devices that stimulate the interconnected growth of fibrous and/or cartilaginous tissue within the disc space in order to stabilize the motion segment, by promoting the growth of living

natural tissue that mimics the characteristics of a natural disc. The primary focus of the Kuslich Application is to stimulate the biologic process of disc repair and reconstitution.

6. The Belef Application describes the process of introducing "fill material" into a bladder within the disc space. The implied and stated purpose of the bladder is to restore the volume of the disc to retain normal spinal motion. There is no stated intent of the Belef Application to biologically stimulate repair and reconstitution of the disc.

7. None of the fill material disclosed in the Belef Application will promote living fibrous and/or cartilaginous tissue within the disc space. The "concentrated growth factors" mentioned were not proposed to repair or reconstitute the disc and are not disposed to perform this function in the application disclosed by Belef.

8. Further, the Belef Application discloses filling a substantially closed, non-porous bladder, wherein the fill materials cannot contribute to the formation of a suitably stable matrix of fibrous growth. This again demonstrates that the Belef Application does not intend nor imply to be a means of disc repair and reconstitution.

9. There is no disclosure in the Belef Application of promoting fibrous and/or cartilaginous tissue within the disc space that mimics the characteristics of a natural disc as claimed in the present invention.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this Third day of January, 2007

Michael Mac Millan MD